4. PROGRAM REGULATIONS

424.401: Introduction

All podiatrists participating in MassHealth must comply with the regulations of the Division governing MassHealth, including but not limited to Division regulations set forth in 130 CMR 424.000 and 450.000.

424.402: Definitions

The following terms used in 130 CMR 424.000 have the meanings given in 130 CMR 424.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 424.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 424.000 and in 130 CMR 450.000.

Controlled Substance – a drug listed in Schedule II, III, IV, V, or VI of the Massachusetts Controlled Substances Act (M.G.L. c. 94C).

Corrective Devices – orthotics, splints, inlays, appliances, and braces that support or accommodate part or all of the foot and serve to restore or improve functions of the foot.

Custom-Molded Shoe – an individually patterned shoe fabricated to meet the specific needs of an individual. A custom-molded shoe is not off-the-shelf, stock, or prefabricated. The shoe is individually constructed by a molded process over a modified positive model of the individual's foot. It is made of leather or other suitable material of equal quality, has removable customized inserts that can be replaced if necessary according to the individual's condition, and has some form of shoe closure.

Drug – a substance containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Emergency – a sudden or unexpected illness or injury or traumatic injury or infection other than athlete's foot or chronic mycosis infecting the nail bed that must be treated promptly to prevent severe pain to the member.

Flexible Adhesive Casting – the application of adhesive tape to orthopedically support or stabilize the foot, or to exert beneficial stress for a structural instability.

Hygienic Foot Care – the trimming of nonpathogenic nails; the cleansing or soaking of the feet; the use of skin creams to maintain skin tone of both ambulatory and bedridden patients; or such other foot care that can be performed by the member or by the nursing facility staff if the member resides in a nursing facility.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, "A"-rated) by the Food and Drug Administration for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

Last – a model that approximates the shape and size of the foot and over which a shoe is made. A last is usually made of wood, plastic, or plaster.

Legend Drug – any drug for which a prescription is required by applicable federal or state law or regulation.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the Division. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 424.419(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 424.000.

Moldable Shoes – off-the shelf, ready-made shoes formed from heat-activated materials. The shoes are molded by a thermo-forming process that first heats the material, then forms it over an individual's foot or a positive model of the individual's foot.

Multiple-Source Drug – a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Nonlegend Drug – any drug for which no prescription is required by federal or state law.

Nonstandard Size (Width or Length) – a shoe size made on a standard last pattern, but which is not part of a manufacturer's regular inventory.

Orthopedic Shoes – shoes that are specially constructed to aid in the correction of a deformity of the musculoskeletal structure of the foot and to preserve or restore the function of the musculoskeletal system of the foot.

Pharmacy On-Line Processing System (POPS) – the on-line, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Split-Size Charge – an additional charge for dispensing an off-the-shelf, medical-grade pair of orthopedic shoes, where one shoe in the pair is a different size or width than the other shoe in the pair.

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken.

424.403: Eligible Members

(A) (1) MassHealth Members. The Division covers podiatry services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.

(2) Age Limitations. In addition to any other restrictions and limitations set forth in 130 CMR 424.00 and 450.000, the Division covers shoes only when provided to eligible MassHealth members under age 21. This age restriction does not apply to therapeutic, moldable, or custom-molded shoes and shoe inserts for members who have severe diabetic foot disease.

(3) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

424.404: Provider Eligibility

Payment for services described in 130 CMR 424.000 is made only to providers who are participating in MassHealth on the date the service was provided or who are otherwise eligible for such payment pursuant to 130 CMR 450.000 and who meet the following requirements.

(A) In State. A podiatrist practicing in Massachusetts must be licensed by the Massachusetts Board of Registration in Podiatry.

(B) Out of State. An out-of-state podiatrist must be licensed by that state's board of registration for podiatrists. The Division pays an out-of-state podiatrist only when services are provided to an eligible Massachusetts member under the following circumstances:

(1) the podiatrist practices outside the border of Massachusetts and provides emergency services to a member;

(2) the podiatrist practices in a community of Connecticut, Maine, New Hampshire, New York, Rhode Island, or Vermont that is within 50 miles of the Massachusetts border and provides services to a member who resides in a Massachusetts community near the border of that state; or

(3) the podiatrist provides services to a member who is authorized to reside out of state by the Massachusetts Department of Social Services.

424.405: Service Limitations and Noncovered Services

(A) Services Limited to Life and Safety. The Division pays only for podiatry services that are certified to be necessary for the life and safety of the member. The Division pays for podiatry services as long as the podiatrist has a written certification on letterhead from the member's primary care physician that attests that such services are medically necessary for the life and safety of the member and that contains a substantiating medical explanation.

(B) Noncovered Services. The Division does not pay for the following:

(1) hygienic foot care as a separate procedure, except when the member's medical record documents that the member cannot perform the care or risks harming himself or herself by performing it. The preceding sentence notwithstanding, payment for hygienic foot care performed on a resident of a nursing facility is included in the nursing facility's per diem rate and is not reimbursable in any case as a separate procedure;

(2) canceled or missed appointments;

(3) services provided by a podiatrist whose contractual arrangements with a state institution, acute, chronic, or rehabilitation hospital, medical school, or other medical institution involve a salary, compensation in kind, teaching, research, or payment from any other sources, if such payment would result in dual compensation for professional, supervisory, or administrative services related to member care;

(4) telephone consultations;

(5) in-service education;

(6) research or experimental treatment;

(7) cosmetic services or devices;

(8) sneakers or athletic shoes;

(9) an additional charge for nonstandard size (width or length) in custom-molded shoes; or

(10) shoes when there is no diagnosis of associated foot deformities.

424.406: Maximum Allowable Fees

The Massachusetts Division of Health Care Finance and Policy (DHCFP) determines the maximum allowable fees for podiatry services. Payment is always subject to the conditions, exclusions, and limitations set forth in 130 CMR 424.000, 442.000, and 450.000. Payment for a service is the lowest of the following:

(A) the provider's usual and customary fee;

(B) the provider's actual charge; or

(C) the maximum allowable fee listed in the applicable DHCFP fee schedule.

424.407: Individual Consideration

(A) Some services listed in Subchapter 6 of the *Podiatrist Manual* are designated "I.C.," an abbreviation for individual consideration. Individual consideration means that a fee could not be established. Payment for an individual-consideration service is determined by the Division's professional advisors based on the podiatrist's descriptive report of the service furnished.

(B) To receive payment for an individual-consideration service, the podiatrist must submit with the claim a report that contains the diagnosis, a description of the condition of the foot, and the length of time spent with the member.

(C) Determination of the appropriate payment for an individual consideration service is in accordance with the following criteria:

(1) the amount of time required to perform the service;
(2) the degree of skill required to perform the service;
(3) the severity and complexity of the member's disease, disorder, or disability;
(4) the policies, procedures, and practices of other third-party insurers, both governmental and private;
(5) prevailing professional ethics and accepted customs of the podiatric community; and
(6) such other standards and criteria as may be adopted from time to time by DHCFP or the Division.

(D) For shoes and corrective devices see 130 CMR 442.421 and 442.422

424.408: Referral

When, during an examination or as a result of laboratory tests, a podiatrist discovers a debilitating or systemic disease (such as diabetes mellitus or ischemia caused by circulatory deficiency), the podiatrist must inform the member that a physician evaluation is necessary and must document this referral in the member's medical record.

424.409: Recordkeeping (Medical Records) Requirements

Payment for any service listed in 130 CMR 424.000 is conditioned upon its full and complete documentation in the member's medical record.

(A) The medical record must contain sufficient data to fully document the nature, extent, and necessity of the care furnished to a member for each date of service claimed for payment, as well as any data that will update the member's medical course. The data maintained in the medical record must also be sufficient to justify any further diagnostic procedures, treatments, and recommendations for return visits or referrals.

(B) Although basic data collected during previous visits (for example, identifying data, chief complaint, or history) need not be repeated in the member's medical record for subsequent visits, the medical records of each service provided by a podiatrist at any location must include, but not be limited to, the following:

(1) the member's name and date of birth;
(2) the date of each service;
(3) the reason for the visit;
(4) the name and title of the person performing the service;
(5) the member's medical history;
(6) the diagnosis or chief complaint;
(7) a clear indication of all findings, whether positive or negative, on examination;
(8) any medications administered or prescribed, including strength, dosage, route, regimen, and duration of use;
(9) a description of any treatment given;
(10) recommendations for additional treatments or consultations, when applicable;
(11) any medical goods or supplies dispensed or prescribed;
(12) any tests administered and their results;
(13) documentation of a treatment plan if subsequent visits are expected;
(14) documentation, when applicable, that the member was informed of the necessity of a physician evaluation;
(15) Life and Safety Certification (see 130 CMR 424.405); and
(16) MassHealth Shoe Medical Necessity Form (if applicable).

424.410: Report Requirements

(A) General Report. A general written report or a discharge summary must accompany the podiatrist's claim for payment when the service is designated "I.C." in Subchapter 6 of the *Podiatrist Manual* or when a service code for an unlisted procedure is used. This report must be sufficiently detailed to enable professional advisors to assess the extent and nature of the services.

(B) Operative Report. For surgery procedures designated "I.C." in Subchapter 6 of the *Podiatrist Manual*, operative notes must accompany the podiatrist's claim. An operative report must state the operation performed, the name of the member, the date of the operation, the preoperative diagnosis, the postoperative diagnosis, the names of the podiatrist and his or her assistants, and the technical procedures performed.

424.411: Office Visits

The Division pays for four types of office visits: initial, limited, extended, and follow-up. The fees vary depending on the type of visit.

(A) The Division pays for one initial visit (the member's first visit to a podiatrist) per member. This visit must include an initial comprehensive history, results of laboratory tests or other findings, whether positive or negative, and identification of both podiatric and general medical problems through vascular, orthopedic, neurological, dermatological, and musculoskeletal examination. The fee for an initial visit includes necessary treatment for relief of symptoms.

(B) The Division pays for one limited visit per member within a 30-day period. A limited visit must include an interval history and examination and treatment of the foot, which may include removal of excrescences; palliative and prophylactic onychial care; treatment of hypertrophied toenails; and electroburring when the record documents that the member has a localized illness, injury, or symptoms involving the foot, including diabetes or peripheral vascular disease.

(C) The Division pays for one extended visit per member within a 30-day period. An extended visit must include the application of flexible adhesive casting, minor modification to shoes, or electric modality physiotherapy. An extended visit may also include the removal of excrescences, palliative and prophylactic onychial care, treatment of hypertrophied or ingrown nails (or both), and other comparable procedures.

(D) The Division pays for one follow-up visit per member per week. A follow-up visit is a return visit for a specific diagnosis (such as warts or an ulcer) in which a brief procedure, such as a dressing change, debridement, or removal of sutures, is performed.

(E) Payment for the removal of an ulcerated keratosis is included in the fees for any type of visit and must not be billed for separately.

(F) The Division pays for either an office visit or a treatment or surgical procedure for the same member on the same date of service but not both.

424.412: Out-of-Office Visits

The Division pays for podiatric care provided in a hospital, a member's home, or a long-term-care facility only when the following conditions are met.

(A) Podiatric care provided in any of the above settings is designed to treat a diagnosed condition, to minimize bed confinement, and to increase the member's activity.

(B) The podiatrist performs and documents a complete evaluation and all necessary treatment for relief of the member's symptoms or for the diagnosed condition.

(C) If further treatment is required, the podiatrist formulates a treatment plan and includes it in the member's medical record. This plan must justify any further diagnostic procedures, additional treatment, return visits, or referrals and must include the following information:

(1) a diagnosis of the member's podiatric condition;
(2) results of X rays and other diagnostic tests, if performed; and
(3) a description of treatment provided and recommendations for additional treatment.

(D) The treatment plan is updated after each visit and details the member's progress.

(E) Documentation of all out-of-office visits, including the member's evaluation, progress, and treatment plan, must be kept either in the podiatrist's office or at the appropriate facility where the service is provided.

(F) Payment is limited to one out-of-office visit per member in a 30-day period in a long-term-care facility or the member's home and two visits in a 30-day period for a member in a hospital setting.

(G) The Division pays for either a visit or a treatment procedure. The Division does not pay for both a visit and a treatment or surgical procedure provided to a member on the same day in the same location.

424.413: Surgical Services and Utilization Management Program Requirements

Surgical procedures must be performed in a podiatrist's office or in a hospital. The Division pays for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.209 are satisfied. Appendix E of the *Podiatrist Manual* contains the name, address, and telephone number of the contact organization for the Utilization Management Program and describes the information that must be provided as part of the review process. Fees for surgical procedures include payment for the initial application of casts, traction devices or similar appliances, anesthesia, surgical tray, suture removal, and up to three visits for postoperative care.

(A) Multiple Procedures. In most circumstances, the Division pays for only one operative procedure in a single operative session. When two separate procedures are performed during the same operative session and neither procedure is designated "S.P." (for separate procedure) (see 130 CMR 424.413(B)), the full maximum allowable fee is paid for the procedure with the largest fee and 50 percent of the maximum allowable fee is paid for each additional procedure.

(B) Separate Procedures. A separate procedure (denoted by "S.P." after the service description in Subchapter 6 of the *Podiatrist Manual*) is reimbursable only when no other procedure is performed during the same operative session, unless one of the exceptions in 130 CMR 424.413(B)(1) through (3) applies.

(1) When, during the same operative session, an additional surgical procedure performed by the same podiatrist is designated "S.P." and requires an unrelated operative incision, the full maximum allowable fee is paid for the procedure with the largest fee and 50 percent of the maximum allowable fee is paid for each additional procedure, unless otherwise provided herein. In the event that two or more procedures are performed during the same operative session, the full maximum allowable fee is paid for only the procedure with the largest fee and 50 percent of the maximum allowable fee is paid for each additional procedure, unless otherwise provided herein.

(2) When, during the same operative session, one or more of the surgery procedures performed by the same podiatrist are designated "S.P." and do not require an unrelated operative incision, the maximum allowable fee is paid for the procedure commanding the largest fee and no payment is made for any other procedure.

(3) When, during the same operative session, all of the surgery procedures performed by the same podiatrist are designated "S.P." and one or more procedures require an unrelated operative incision, payment is determined by individual consideration.

424.414: Surgical Assistants

(A) MassHealth pays a surgical assistant at 15 percent of the allowable fee for the surgical procedure. MassHealth will not pay for a surgical assistant if a surgical assistant is used in less than five percent of the cases for that procedure nationally. In addition, MassHealth will not pay for a surgical assistant if the surgery services were provided in a teaching hospital that has an approved training program related to the medical specialty required for the surgical procedure(s) and a qualified resident available to perform the services. If no qualified resident is available to perform the services, MassHealth will pay for a surgical assistant if the member's medical record documents that a qualified resident was unavailable at the time of the surgery.

(B) A surgical assistant must meet the requirements for provider eligibility specified in 130 CMR 424.404.

424.415: Radiology Services

(A) MassHealth pays for radiology services when the services are needed to confirm the diagnosis of a bony or calcific disorder, to detect soft-tissue disorders, or to detect foreign bodies.

(B) Payment for radiology services is not included in the fees for visits and should be claimed separately.

(C) All radiology equipment used in providing these services must be inspected and approved by the Massachusetts Department of Public Health.

(D) MassHealth pays a podiatrist for radiology services only when the service is provided in the podiatrist's office and only when the films are developed and read in the podiatrist's office.

(E) All X rays must be labeled with the member's name, the date of examination, and the nature of the examination in addition to the information required in 130 CMR 424.409.

(F) MassHealth pays one maximum allowable fee for a routine study of a particular section of an extremity regardless of the number of X-ray views. An additional fee may be claimed only when a comparison study is necessary.

424.416: Clinical Laboratory Services

(A) MassHealth pays the podiatrist only for laboratory tests listed in the *Podiatrist Manual* and only when the tests are administered and analyzed in the podiatrist's office. MassHealth pays a certified independent clinical laboratory or hospital-licensed clinical laboratory if the laboratory tests are performed at the clinical laboratory.

(B) MassHealth pays for clinical laboratory tests that are necessary for the diagnosis or treatment of conditions of the foot only.

(C) Only the following laboratory tests may be administered without prior authorization:
(1) complete blood count or any of the separate components of such an analysis, including red cell count, white cell count, or hemoglobin;
(2) hematocrit;
(3) fungus culture;
(4) sensitivity, culture, and colony count;
(5) fasting blood sugar;
(6) platelet count;
(7) uric acid;
(8) complete urinalysis; and
(9) combination urinary dip stick (pH, blood, ketones, glucose, nitrites).

(D) The podiatrist must include the following information with any specimen submitted to a certified independent clinical laboratory or hospital-licensed clinical laboratory:
(1) a signed request for the laboratory services to be performed;
(2) the member's identification number, which appears on the member's MassHealth card; and
(3) the podiatrist's name, address, and provider number.

424.417: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. MassHealth pays for legend drugs and nonlegend drugs only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription, regardless of drug schedule, must contain the prescriber’s unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number on the prescription.

(B) Emergencies. When the pharmacist determines that an emergency exists, MassHealth will pay a pharmacy for at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations. Emergency dispensing to a MassHealth member who is enrolled in the Controlled Substance Management Program (CSMP) must comply with 130 CMR 406.442(C)(2).

(C) Refills.

(1) MassHealth does not pay for prescription refills that exceed the specific number authorized by the prescriber.

(2) MassHealth pays for a maximum of 11 monthly refills, except in circumstances described at 130 CMR 424.417(C)(3).

(3) MassHealth pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 424.417(D).

(4) MassHealth does not pay for any refill dispensed after one year from the date of the original prescription.

(5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(6) MassHealth does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

(D) Quantities.

(1) Days' Supply Limitations. MassHealth requires that all drugs be prescribed and dispensed in at least a 30-day supply, but no more than a 90-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 424.417(D)(2).

(2) Exceptions to Days' Supply Limitations. MassHealth allows exceptions to the limitations described in 130 CMR 424.417(D)(1) for the following products:

(a) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;

(b) drugs that, in the prescriber's professional judgement, are not clinically appropriate for the member in a 30-day supply; .

(c) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;

(d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 90-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);

(e) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments); and

(f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs).

(E) Prescription-Splitting. Providers must not split prescriptions by filling them for a period or quantity less than that specified by the provider. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. MassHealth considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

424.418: Pharmacy Services: Covered Drugs

The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, MassHealth pays only for legend drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8.

424.419: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. MassHealth pays no more for a brand-name interchangeable drug product than its generic equivalent, unless:

(1) the prescriber has requested and received prior authorization from MassHealth for a nongeneric multiple-source drug (see 130 CMR 424.420); and

(2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(B) Drug Exclusions. MassHealth does not pay for the following types of drugs or drug therapy:

(1) Cosmetic. MassHealth does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.

(2) Cough and Cold. MassHealth does not pay for legend or nonlegend drugs used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless they are dispensed to an institutionalized member.

(3) Fertility. MassHealth does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. MassHealth does not pay for any drug used for the treatment of obesity.

(5) Smoking Cessation. MassHealth does not pay for any drug used for smoking cessation.

(6) Less-Than-Effective Drugs. MassHealth does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

(7) Experimental and Investigational Drugs. MassHealth does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 424.419(B). The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 424.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. MassHealth will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List accordingly. See 130 CMR 450.303.

(2) MassHealth does not pay for the following types of drugs or drug therapy without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH);

(b) nongeneric multiple-source drugs;
(c) drugs used for the treatment of male or female sexual dysfunction;
(d) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. MassHealth, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993; and
(e) topical acne products for members aged 21 or older. MassHealthpays for topical acne products for members under age 21, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

(3) MassHealth does not pay any additional fees for dispensing drugs in a unit-dose distribution system.

(4) MassHealth does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as MassHealth determines to be consistent with current medical evidence.

(5) MassHealth does not pay for any drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307.

424.420: Pharmacy Services: Insurance Coverage

(A) Managed Care Organizations. MassHealth does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.

(B) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill MassHealth for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether MassHealth generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 424.419(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from MassHealth in order for the pharmacy to bill MassHealth for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq.

424.421: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 424.418 and 424.419(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions for requesting prior authorization in Subchapter 5 of the *Podiatrist Manual*. If MassHealth approves the request, it will notify both the podiatrist and the member.

(C) MassHealth authorizes at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) MassHealth acts on requests for prior authorization for a prescribed drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements of other health insurers.

(E) The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 424.417 through 424.421. MassHealth will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

424.422: Pharmacy Services: Member Copayments

MassHealth requires under certain conditions that members make a copayment to the dispensing pharmacy for each original prescription and for each refill for all drugs (whether legend or nonlegend) covered by MassHealth. The copayment requirements are detailed in 130 CMR 450.130.

424.423: Drugs Dispensed in Provider's Office

Drugs dispensed in the office are payable at the podiatrist's actual acquisition cost if this cost is more than $1.00. Claims for dispensing drugs must include the name of the drug or biological, the strength, and the dosage. A copy of the invoice showing the actual acquisition cost must be attached to the claim form, and must include the National Drug Code (NDC). Claims without this information will be denied.

424.424: Shoes and Corrective Devices

(A) MassHealth pays for only those shoes listed in Subchapter 6 of the *Podiatrist Manual*.

(B) For shoes, providers must submit with their claim a copy of the completed MassHealth Shoe Medical Necessity Form and a copy of the Life and Safety Certification from the primary care physician. (See 130 CMR 424.405.)

(C) MassHealth does not pay for casting materials used in the molding of orthotic shoes or corrective devices. The cost of these materials is included in the fee for prescribing and providing the shoe or corrective device.

REGULATORY AUTHORITY

130 CMR 424.000: M.G.L. c. 118E, §§7 and 12.